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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,988	05/16/2005	Lasse Leino	OHMAN-002	1914
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JAMES C. LYDON				
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SUITE 100				
ALEXANDRIA, VA 22314				
EXAMINER				
SHOMER, ISAAC				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
09/14/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,988

Applicant(s)

LEINO ET AL.

Examiner

ISAAC SHOMER

Art Unit

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/C)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date: _____

DETAILED ACTION

Applicants' arguments, filed 18 August 2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

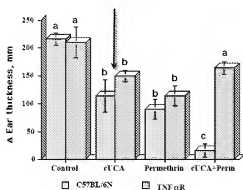
Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Prater ("Immunotoxicity of Dermal Permethrin and Cis-Urocanic Acid: Effects of Chemical Mixtures in Environmental Health" PhD Thesis, 8 March 2002, 191 numbered pages) in view of Wille et al. (US Patent 5,843,979).

Prater examined the effects of intradermal cis-urocanic acid (abbreviated cUCA), as of Prater, page ii, top of page. Prater teaches that five day exposure to cis-urocanic acid caused persistent decreased contact hypersensitivity responses, as of Prater, page ii, middle of page. In one embodiment, Prater teaches that cis-urocanic acid (with no other drugs) causes a reduction in contact hypersensitivity (as measured by ear

thickness of mice), as of Prater, page 164 Figure 2, and caption (figure is reproduced below, with an arrow added by the examiner pointing to the relevant column), wherein the left column is a control, and the second from left column describes the administration of cis-urocanic acid alone.



Cis-urocanic acid was administered topically, as of Prater, page 164, caption of figure 5.2.

Prater is silent as to the pH of the vehicle in which cis-urocanic acid was delivered.

Wille et al. (hereafter referred to as Wille) teaches a method and composition for preventing skin irritation by delivering cis-urocanic acid via a dermal or transdermal mechanism, as of Wille, abstract. Said transdermal preparation may have a pH of between 1 and 12, as of Wille, column 12, lines 60-66.

It would have been prima facie obvious for one of ordinary skill in the art to have administered cis-urocanic acid, as of Prater, in a formulation with a pH of between 1 and 12, as of Wille. The skilled artisan would have been motivated to have formulated cis-urocanic acid into a formulation with such a pH range, as such a vehicle would have

predictably delivered cis-urocanic acid dermally or transdermally with a reasonable expectation of success.

The pH range taught by Wille does not read on the claimed pH range of 6.1 to 7.0, but does not read on this range. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Claims 31-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wille et al. (US Patent 5,843,979).

Wille et al. (hereafter referred to as Wille) teaches a method for inhibiting skin irritation by administration of cis-urocanic acid transdermally (a form of local administration), as of Wille, abstract. In one embodiment, Wille teaches the suppression of contact hypersensitivity by purified cis-urocanic acid when applied in a gel form to the skin of mice, as of Wille, Example 9, column 20 lines 32-57, wherein cis-urocanic acid inhibits contact sensitivity, as of Wille, Table X, column 21 lines 18-42. Said transdermal preparation may have a pH of between 1 and 12, as of Wille, column 12, lines 60-66.

The specific combination of features claimed is disclosed within the broad generic ranges taught by the reference but such "picking and choosing" within several variables does not necessarily give rise to anticipation. Coming Glass Works v. Sumitomo Elec., 868 F.2d 1251, 1262 (Fed. Circ. 1989). Where, as here, the reference

does not provide any motivation to select this specific combination of variables, specifically a method of using cis-urocanic acid to treat contact hypersensitivity, and a method of using a formulation with a pH in the range of 1-12, anticipation cannot be found.

That being said, however, it must be remembered that "[w]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious". KSR v. Teleflex, 127 S.Ct. 1727, 1740 (2007) (quoting Sakraida v. A.G. Pro, 425 U.S. 273, 282 (1976)). "[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious", the relevant question is "whether the improvement is more than the predictable use of prior art elements according to their established functions." (Id.). Addressing the issue of obviousness, the Supreme Court noted that the analysis under 35 USC 103 "need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." KSR v. Teleflex, 127 S.Ct. 1727, 1741 (2007). The Court emphasized that "[a] person of ordinary skill is... a person of ordinary creativity, not an automaton." Id. at 1742.

Consistent with this reasoning, it would have obvious to have selected various combinations of various disclosed ingredients specifically a method of using cis-urocanic acid to treat contact hypersensitivity, and a method of using a formulation with

a pH in the range of 1-12, from within a prior art disclosure, to arrive compositions “yielding no more than one would expect from such an arrangement”.

The pH range taught by Wille does not read on the claimed pH range of 6.1 to 7.0, but does not read on this range. While the prior art does not disclose the exact claimed values, but does overlap: in such instances even a slight overlap in range establishes a *prima facie* case of obviousness. In re Peterson, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003).

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ISAAC SHOMER whose telephone number is (571)270-7671. The examiner can normally be reached on 8:00 AM - 5:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ISAAC SHOMER/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612